

REMARKS

Claims 8-28 have been cancelled. Claims 1 and 2 have been amended. Thus, claims 1-7 remain pending in the present application. No new matter has been added.

The Examiner objected to claim 2 because of the term "base membrane." In view of the amendment to claim 2, withdrawal of this rejection is requested.

Claims 1-7 stand rejected under 35 U.S.C. § 112, ¶1, as failing to comply with the written description requirement. According to the Examiner, the limitation that the "seating portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed" is new matter. Applicants respectfully disagree. Figures 3 and 4 uses dotted lines to demarcate seating portion 108 on membrane 102. The region 108 clearly shows that it occupies a thin band on the edge of the membrane 102; even a cursory, glancing view of the figures reveals portion 108 to occupy a minority of membrane 102. Nor is it necessary for the actual word "minority" or phrasings such as "less than 50 percent" to appear in the text of the specification in order to establish support for this limitation. If that is the position of the Examiner, then Applicants request that the Examiner cite to some authority requiring such strict textual support. Indeed, despite the absence of the word "minority" in the specification, the specification nevertheless provides textual support for this limitation. Specifically, paragraph [0030] of the specification states that "compression strains exerted by the housing 30 to retain the membrane 102 in place are concentrated on the seating portion 108, which in this exemplary embodiment is an annular region *at the periphery of the membrane 102.*" (Emphasis added). The same paragraph of the specification also states that the "seating portion 108 in this example *takes up the annular periphery of the elliptical membrane* in the range of 0.045-0.055 inches." (Emphasis added). If the seating portion is limited to the annular periphery, as is expressly stated in the specification and illustrated in the drawings, then it is not inappropriate to consider seating portion as occupying a minority of the membrane 102. Accordingly, withdrawal of this rejection is requested.

Claims 1-7 stand rejected under 35 U.S.C. § 112, ¶2, as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner finds confusing the recitation that the thickness of the seating portion is greater than a thickness

of the lumen occluding portion. Applicants have removed this language from claim 1, and have added to claim 2 the limitation that “a thickness of the flow control membrane at the seating portion is greater than a thickness of the lumen occluding portion.” This increase in thickness is a consequence of stacking annular base membrane 104 onto seating portion 108 of flow control membrane 102, as seen in Figures 3 and 4. Accordingly, withdrawal of this rejection is requested.

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,205,834 to Moorehead in view of U.S. Patent No. 3,811,466 to Ohringer. The Examiner relies on Ohringer to show the limitation “wherein the mounting portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed.” The Examiner needs Ohringer because the Examiner concedes that in Moorehead, a majority, not minority, of a surface area of a diaphragm 124 is covered by a disc 120. This is so because of the small size of an opening 132 of the disc 120 in relation to the overall surface area of the disc 120. The reasoning of the Examiner is substantially the same as before. Namely, the Examiner argues that (1) Ohringer teaches varying the diameter d_3 of a control plate 19, (2) the teaching of Ohringer can be viewed as a teaching to vary the diameter of an opening around a slit of an adjacent membrane, and (3) therefore, analogously, the teaching of Ohringer supports enlarging the diameter of the opening 132 of the disc 120 in Moorehead to such an extent that only a minority of adjacent the diaphragm 124 (regarded as meeting the “flow control membrane”) is covered by the surface of disc 120.

As before, Applicants continue to disagree with this analysis. Ohringer does not support enlarging the opening 132 of the disc 120 in Moorehead to the extent necessary to meet the claim limitation. In Ohringer, a worry is the tearing of a slit 31 of a diaphragm 17 that may occur due to a powerful flow of fluid therethrough. The likelihood of tearing increases if an opening 33 of an adjacent control plate 19 is large enough that the entire length of the slit 31 is exposed to the fluid flow. Specifically, Ohringer states that “[t]he length L_1 [of the slit 31 in disc 124] is preferably the same as, or longer than, the inside diameter d_1 of flange 13. This is because if L_1 is lesser than d_1 , the slit has a tendency of tearing at the ends after a certain duration use.” Column 2, lines 39-43. Therefore, a correct application of the Ohringer teaching to Moorehead would be mindful of this limitation, since Moorehead also employs a slit diaphragm 124 that is presumably vulnerable to the type of tearing noted by Ohringer. A person of ordinary skill, then, would understand that Ohringer would not support expanding the diameter of the opening 132 in Moorehead to such an extent that the full length of the slit in the adjacent diaphragm 124 would

be exposed to the fluid flow. If Ohringer does not support expanding the diameter of the opening 132 to completely expose the slit of diaphragm 124 in Moorehead, then, given the dimensions of these elements as depicted in the drawings, Ohringer does not support expanding the opening 132 to an extent that would cause only a minority of a diaphragm 124 to be covered by the disc 120.

Even if Ohringer did not explicitly limit the extent to which an opening of a disc could be expanded, the modification to the opening 132 of the disc 120 as proposed by the Examiner still would not find any support. In Ohringer, the purpose of expanding the size of the opening d3 is to increase the portion of the slit 31 exposed to a fluid flow. Column 2, lines 50-51. Thus, Ohringer supports expanding the size of the opening d3 only up to the point where opening d3 completely exposes the slit. Any further expansion would be superfluous with respect to the flow control purpose and thus unsupported. In applying this teaching to Moorehead in a manner consistent with Ohringer, the maximum extent to which one of ordinary skill in the art would expand the opening 132 would be to fully expose the slit 146 in a diaphragm 124. Given the small size of the slit 142 relative to the diameter of the disc 120, one of ordinary skill in the art could expand the opening 132 of the disc 120 to completely expose slit 146 without expanding it enough so that only a minority of the diaphragm 124 would be covered by the disc 120. Any further expansion of the opening 132 beyond the point needed to expose more of the slit 146 would be unrelated to fluid flow control and thus outside the bounds of the Ohringer teaching.

Another reason why claim 1 is patentable over the combination of Moorehead with Ohringer is based on the limitation “the flow control membrane including a seating portion *at which the flow control membrane is coupled to the housing....*” This cannot be met by either Moorehead or Ohringer because in both of these references their respective slit diaphragms are pressed against an adjacent disc, not a housing. This limitation quoted above requires the “seating portion” to be “coupled to the housing.” If, as is the case with the two references, the purported “flow control membrane” (the slit diaphragm 124 in Moorehead and the slit diaphragm 17 in Ohringer) of these references rests against only an adjacent disc (the control plate 19 in Ohringer and the flex control disc 120 in Moorehead), then no portion of the purported “flow control membrane” of these references can be correctly said to be “coupled to the purported “housing” (e.g., valve housing parts 44, 46 of housing 42 in Moorehead).

In responding to this argument in the Final Office Action, the Examiner acknowledges that Ohringer is concerned with the tearing of the tearing of slit 31, but does not attach to this

concern the same weight as Applicants. In particular, the Examiner relies on the teaching that the diameter d3 of the plate 19 of Ohringer can be varied. The Examiner does not believe that the concern regarding tearing affects the extent to which diameter d3 can be varied. According to the Examiner, if the diameter d3 can be varied, then it must mean that it can be expanded to such an extent that plate 19 covers only a minority of the adjacent membrane. The Examiner does not explain why the concern over tearing would not serve as a limitation on the extent to which d3 can be enlarged. A reference is to be considered for all it teaches; here, the Examiner has not abided by this basic rule for interpreting references. If the expansion of d3 permits more fluid to impinge on the adjacent diaphragm 17, that means that the risk of tearing diaphragm 17 increased in proportion to the increase of d3. If that is the case, then, contrary to what the Examiner believes, the concern over tearing does serve to limit the extent to which the diameter d3 can be expanded. If expanding the diameter d3 so that only a minority of plate 19 occupies diaphragm 17, then it follows that, all other relevant risk factors being held constant, the risk of tearing has been elevated to a maximum degree (at least that portion of the risk directly influenced by the diameter d3). But such a maximization of risk cannot be what one of ordinary skill in the art would glean from the references, given the expressed desire to limit the risk of tearing. Accordingly, Applicants maintain their argument that the combination of Morehead and Ohringer does not meet claim 1.

Therefore, for at least these reasons, claim 1 is patentable over the combination of Moorehead and Ohringer. As for claims 2-4, these claims are patentable for at least the same reasons given in support of claim 1.

Claims 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Moorehead in view of U.S. Patent No. 5,944,698 to Fischer et al. Since Fischer does not overcome the deficiencies noted above with respect to Moorehead, Applicants submit that claims 5-7 are patentable for at least the same reasons given above.

In light of the foregoing, Applicants respectfully submit that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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